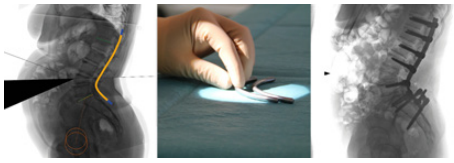
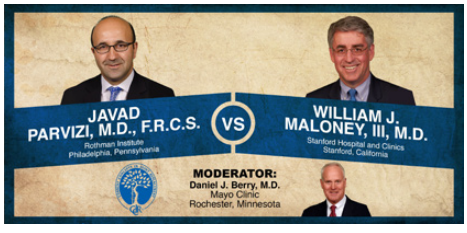
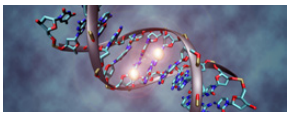
VOLUME 11, ISSUE 3 | JANUARY 20, 2015

Orthopedics This Week

WEEK IN REVIEW







BREAKING NEWS

For all news that is ortho, read on.

Orthopedic Power Rankings

Robin Young's Entirely Subjective Ordering of Public Orthopedic Companies

THIS WEEK: The market's confused. U.S. retail sales fell in December by the most in 11 months. But consumer sentiment is up. U.S. wholesale prices fell. And there's an absolute rout in oil prices happening. What's going on? Deflation—which has been the central economic issue since 2008. Believe it or not, deflationary pressures are still here. So watch the Fed back away from raising rates and hope the Europeans follow suit.

RANK	LAST WEEK	COMPANY	TTM OP MARGIN	30-DAY PRICE CHANGE	COMMENT
1	1	Integra LifeSciences	12.57%	9.86%	Not only is IART the least expensive equity in orthopedics, but it is also one of the best performing.
2	2	Stryker	11.52	(0.41)	Now the fifth cheapest equity in orthopedics, pretty much because they want to buy SNN.
3	6	ConMed	10.51	9.17	Had a great JP Morgan meeting last week in San Francisco. Investors like the new team and look forward to a revived CNMD.
4	3	Exactech	10.44	(1.37)	Second least expensive equity in orthopedics and, as always, one of the most volatile equities.
5	5	Zimmer	29.12	4.54	For its final year before Biomet, ZMH is expected to report essentially flat sales of $1.25 billion for Q4.
6	8	Medtronic	28.84	0.12	Still #1 supplier of spinal implants and biologics in the world and generating a solid 29% return on sales.
7	10	Johnson & Johnson	28.44	(0.03)	Love it, Goldman downgrades JNJ to "sell." Really? Now that the stock is finally getting cheap again. Sell?
8	4	NuVasive	8.01	2.43	Keith Valentine, one of the smartest (and tallest) med device managers in the world is leaving. Pat Miles and Matt Link will pick up the slack.
9	9	Globus Medical	29.68	(0.25)	Pre-announces a huge 11.5% sales increase for Q4. GMED is ending the year on an upswing.
10	7	Smith & Nephew	19.92	8.18	Everyone is buying ahead of the news. But what if this price run delays or kills a deal with SYK?

Robin Young's Orthopedic Universe

TOP PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	Aurora Spine	ASG	$1.55	$21	15.35%
2	CryoLife	CRY	$12.13	$339	15.09%
3	Bacterin Intl Holdings	853	$2.99	$20	13.70%
4	Integra LifeSciences	IART	$56.62	$1,856	9.86%
5	ConMed	CNMD	$47.25	$1,301	9.17%
6	LDR Holding Corp.	LDRH	$34.65	$903	8.62%
7	Smith & Nephew	SNN	$35.98	$16,082	8.18%
8	Alphatec Holdings	ATEC	$1.40	$139	7.69%
9	Zimmer Holdings	ZMH	$117.00	$19,814	4.54%
10	NuVasive	NUVA	$48.04	$2,260	2.43%

WORST PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	MiMedx Group	MDXG	$8.69	$929	-20.64%
2	MicroPort Scientific	853	$0.41	$585	-9.87%
3	Wright Medical	WMGI	$25.56	$1,305	-8.45%
4	Tornier N.V.	TRNX	$24.93	$1,219	-5.96%
5	RTI Biologics Inc	RTIX	$4.95	$282	-4.81%
6	Orthofix	OFIX	$29.53	$544	-1.80%
7	Exactech	EXAC	$22.38	$309	-1.37%
8	Stryker	SYK	$92.45	$34,976	-0.41%
9	Globus Medical	GMED	$24.17	$2,368	-0.25%
10	Johnson & Johnson	JNJ	$104.04	$291,219	-0.03%

LOWEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	Johnson & Johnson	JNJ	$104.04	$291,219	17.41
2	Medtronic	MDT	$72.76	$71,619	18.22
3	Exactech	EXAC	$22.38	$309	19.63
4	Zimmer Holdings	ZMH	$117.00	$19,814	20.17
5	Globus Medical	GMED	$24.17	$2,368	25.14

HIGHEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	MiMedx Group	MDXG	$8.69	$929	866.49
2	RTI Biologics Inc	RTIX	$4.95	$282	414.47
3	Orthofix	OFIX	$29.53	$544	188.65
4	NuVasive	NUVA	$48.04	$2,260	124.00
5	Smith & Nephew	SNN	$35.98	$16,082	63.91

LOWEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	Exactech	EXAC	$22.38	$309	1.31
2	CryoLife	CRY	$12.13	$339	1.38
3	Globus Medical	GMED	$24.17	$2,368	1.85
4	ConMed	CNMD	$47.25	$1,301	2.03
5	Integra LifeSciences	IART	$56.62	$1,856	2.23

HIGHEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	MiMedx Group	MDXG	$8.69	$929	57.77
2	RTI Biologics Inc	RTIX	$4.95	$282	27.63
3	NuVasive	NUVA	$48.04	$2,260	10.85
4	Orthofix	OFIX	$29.53	$544	10.25
5	Smith & Nephew	SNN	$35.98	$16,082	6.87

LOWEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	Bacterin Intl Holdings	BONE	$2.99	$20	0.58
2	Alphatec Holdings	ATEC	$1.40	$139	0.68
3	RTI Biologics Inc	RTIX	$4.95	$282	1.12
4	Exactech	EXAC	$22.38	$309	1.25
5	Orthofix	OFIX	$29.53	$544	1.37

HIGHEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	TiGenix	TIG.BR	$0.63	$101	17.65
2	MiMedx Group	MDXG	$8.69	$929	9.62
3	LDR Holding Corp.	LDRH	$34.65	$903	8.09
4	Globus Medical	GMED	$24.17	$2,368	5.14
5	K2M Group Holdings	KTWO	$21.07	$783	4.97

PSR: Aggregate current market capitalization divided by aggregate sales and the calculation excluded the companies for which sales figures are not available.

Employee Anxiety and Weakened Biomet Create Uncertainty in Warsaw

BY WALTER EISNER

Employee anxiety, a bribery investigation, regulatory hurdles and a less pretty Biomet, Inc. are challenging Zimmer Holdings Inc.'s CEO, Dave Dvorak as he drives the merger between the two Warsaw, Indiana orthopedic giants.

When Zimmer offered $13.35 billion for the pretty girl down the street in April, Biomet had a net worth higher than it does today. Its sales were rising faster than in the most recently reported quarter and a federal investigation of bribery charges in Brazil and Mexico put a blemish on the girl's reputation.

Today, headlines in trade journals ask if the planned deal is in trouble. Nothing coming from the leaders of Zimmer or Biomet even remotely hint at any trouble with the deal or if any discussions are taking place to re-price the deal. Dvorak continues to tell analysts the company expects regulatory approvals in the first quarter of 2015.

But a "sense of uncertainty has crept over the economy of Warsaw, Indiana," said a recent *New York Times* article.

Dave Dvorak

Drue DeAngelis

Photo creation by RRY Publications / Sources: Pixabay and logos courtesy of the companies

DeAngelis' Advice on Musical Chairs

While the Securities Exchange Commission (SEC), European regulators and U.S. Justice Department officials grind through their legal requirements to bless the deal, the employees of the two companies continue to wait to see which chairs they will occupy when the music stops sometime in the spring.

In April 2014, well-known industry executive search consultant, Drue DeAngelis, wrote one of the 2014 top read stories in *OTW* as he outlined what employees of Zimmer and Biomet can expect as the companies merge. He had some personal knowledge. It was 15 years ago that he was laid off by Stryker Corporation right before Christmas, almost a year to the date of the acquisition of Howmedica Osteonics Corporation.

On December 22, 2014 DeAngelis wrote that not much has happened since the announcement of the deal, "apart from the typical script being played repeatedly that 'it's business as usual' under the new Zimmer-Biomet banner." He notes that after the transition team was announced, it appears the early "big winner" is Biomet with Adam Johnson, Dan Williamson and Dave Nolan being selected as the new Group Presidents leading the transition."

Reductions in Force

So now what?

There will be some big announcements coming out soon, guesses DeAngelis. Those announcements, he says, will signal the next phase of the transition and the first wave of several "Reductions in Force [RIFs]." "Unfortunately, no one is protected from a RIF. All of the typical protected classes of employees are fair game during this type of transaction, so don't assume that you are immune."

DeAngelis says Zimmer will try to keep these episodes on as small a scale as possible to avoid a disruption in the field and mass exodus. "They will count on the self-preservation instincts of those who get ousted to 'keep quiet and go along' in order to receive their severance packages."

Waves of Winners and Losers

The first wave, says DeAngelis, will be the Division Presidents followed shortly thereafter by the VP's. "They will allow the dust to settle a bit before the next level hits the AVP's [Assistant Vice Presidents] and subsequently Sales Directors. Each layer of retained leaders will be called upon to select the next level's winners and losers. The most obvious redundancies exist in the field but before the RIF reaches the Distributor/Branch level, there will be the thinning of sales leadership. They will endeavor to keep most of the 'high potential leaders' even if it means reassigning them to another role or division."

"For some, this will mean they have to endure a demotion, but their only other option is an exit plan. Due to the obvious redundancies across the board, the leaders who make these decisions will do their best to mitigate the risks of losing business. Yet as fiercely political as this may become, this will prove increasingly challenging. Ideally by combining two companies, they hope to enjoy the 'One Plus One Equals Two' outcome when the dust settles. However, this takes incredible finesse to accomplish and most companies fall short of achieving it. Subsequently, their 'One Plus One' will most likely equal 'Less than Two,' and this begs the question 'how much less?'"

Competitor Feeding Frenzy

"Let's face it, if you're not kept around, you really don't care too much about how things play out, but the business that is lost will go to those companies who stand to capitalize on this feeding frenzy."

Employees shouldn't expect this process to follow a logical progression of winners and losers. "If you end up on the wrong side, you shouldn't view this as a failure. Only time will tell, but you may be significantly better off outside of the new Mega Zimmer-Biomet rather than within."

Pure Politics

Employees also shouldn't expect any of it to make sense.

"There will be those who are retained that make perfect sense given who's in charge. And yet, there will be some that make no sense whatsoever. You can drive yourself crazy trying to make sense of the new organizational structure. Invariably, many of the decisions don't make sense given the limited information that you have at your disposal. This is because you aren't privy to the behind the scenes playbook. Some of the new appointments will simply fall under the category of 'pure politics.'"

"The reality is that the decision making process is extremely difficult in most cases. And what makes perfect sense to one person is a mystery to another. To some it will seem random and although some will be surprised by who keeps their jobs, others will be shocked by who is sent packing. This is simply the nature of these proceedings. All the while, upper management tries to contain the damage and keep the people focused upon the goal of stabilizing the business."

Life After ZimmerBiomet

There is life after ZimmerBiomet, says DeAngelis. "Some of you will learn that your loyalty was not valued as you would have expected and you will be disappointed if not disillusioned. Some of you will take it very personally while others will feel a sense of relief as seeing the future in the Mega Ortho company as something they never signed up for."

His advice to employees who have been RIFed is to let the holidays pass without panicking or trying to secure your next gig. "Whenever your RIF should happen, if you are caught up in one of the waves, take a reasoned and calculated approach to finding your next job. Try not to take it too personally. I know just how difficult that is, but nothing is gained through attacking people and making a scene. Keep a positive outlook and anticipate good things to come in your near future. A fresh start and perspective may be exactly what you needed and what better time than the end of a year."

Biomet's Bribery Complication

While Dvorak tries to keep employees calm, Biomet isn't making life easier for him after *The New York Times* reported on December 23, 2014 of "confidential documents" that said possible acts of bribery "may complicate" the deal.

An email from an anonymous whistleblower said that distributors hired by Biomet were paying "kickbacks" to government doctors in Mexico and Brazil.

Biomet reported in a July 2014 SEC filing that it had been subpoenaed by the SEC regarding "certain alleged improprieties" it had discovered in its opera-

tions in Brazil and Mexico in October 2013. Biomet disclosed the "improprieties" to the Justice Department and SEC in April 2014. The company said it had terminated, suspended or otherwise disciplined employees and executives involved.

It's not the first bribery scandal for Biomet. Back in March 2012, Biomet entered into a deferred prosecution agreement and agreed to pay nearly $23 million in settlements with the U.S. Justice Department and the SEC over allegations that the company bribed healthcare providers in Argentina, Brazil and China.

The *Times* article noted that Biomet disclosed the problem to Zimmer before the merger deal. But a steep penalty for Biomet might alter the price of that deal.

Another Deferred Prosecution Deal Possible

Lawyers "briefed" on the matter told the *Times* that "the Justice Department has discussed the possibility of reaching a so-called deferred prosecution agreement with Biomet that would withhold criminal charges in exchange for certain concessions. Under that plan, prosecutors would impose criminal charges only on Biomet's Brazilian and Mexican subsidiaries."

Biomet's Slowing Hip and Knee Sales

In addition to this newest allegation of bribery, Biomet also isn't selling hips and knees as fast as it was when employees were still in full competition out in the field with their future Zimmer colleagues or bosses.

On January 6, 2015, Biomet announced that hip and knee sales for its second fiscal quarter of 2015 each rose by only 0.1% on a reported basis. In fact, U.S. knee sales shrank slightly. For the same quarter in 2014, knee and hip sales climbed 6.6% and 2.3%, respectively. Overall sales of $843.6 million only rose 2.2%, compared to a 4.5% rise last year. Spine revenue from the Lanx acquisition accounted for an 18.7% rise in sales. Net sales in the U.S. climbed 3.9% while European sales fell 2.7%.

Needham & Co. analyst Mike Matson said that Biomet's growth slowed from the prior quarter in two of its three geographic regions and five of its six product categories. He thinks this could indicate that orthopedic market growth slowed and/or that Biomet lost share, possibly due to disruption ahead of its merger with Zimmer.

Wells Fargo analyst Larry Biegelsen said it was unclear whether the slowdown was Biomet-specific or indicative of a broader market slowdown. "Based on our initial checks, we believe it was likely Biomet-specific."

Biomet also took a step back in value as its net worth dropped from $5.47 billion in May 2014 to $5.43 in November 2014.

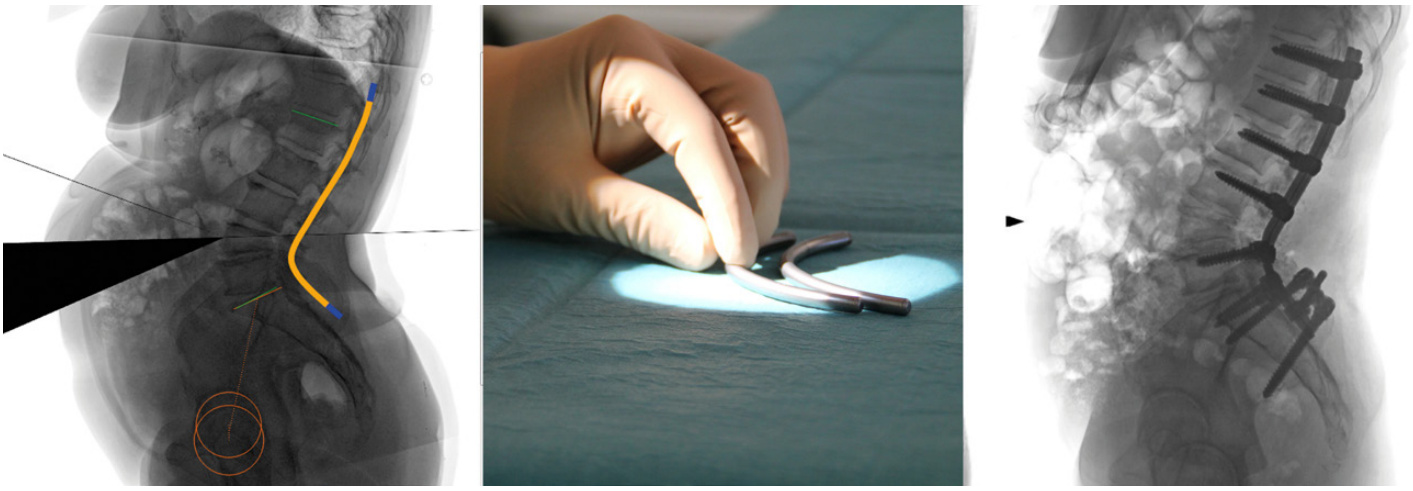
So the girl courted by Zimmer last year is looking slightly less pretty this year. But at the end of the dance, a promise is a promise and Zimmer is still taking Biomet home. ♦

Biomet 2Q 2015	Sales $ in million	% Change
Total Reported Sales	**$843.6**	**2.2%**
Knees	264.3	0.1%
Hips	168.0	0.1%
Sports, Extremities, Trauma	160.0	0.2%
Spine & Bone Healing	124.5	18.7%
Dental	67.6	down 4%
Biologics and Other	58.6	0.5%

Source: Biomet, Inc.

FREE Software Accurately Predicts Surgical Outcomes 97% of the Time // 86% of Soldiers Return to Duty After Joint Surgery // Discs to Grow OUTSIDE the Body?

BY ELIZABETH HOFHEINZ, M.P.H., M.ED.



Surgimap Software and Medicrea UNiD Rod / Source: Medicrea Group

FREE Software Accurately Predicts Surgical Outcomes 97% of the Time "Why didn't they do it before," you might think. In the words of Frank Schwab, M.D., his team succeeded by connecting the dots. Dr. Schwab, Chief of the Spinal Deformity Service at New York University's Langone Medical Center, recently implanted the first customized osteosynthesis rod precisely designed and manufactured to properly realign the individual's spine. Dr. Schwab is the founder/CEO, board member, and a significant equity holder of Nemaris, Inc., developer of Surgimap, the dedicated software platform used by Medicrea Group for producing this new patient specific device (UNiD rod).

Dr. Schwab told *OTW,* "Even in residency I was drawn to spinal deformity because there wasn't much clarity, and thus great opportunity to optimize outcomes or standardize approaches for dealing with a wide variety of deformity problems. As data emerged from multicenter studies we began to see that there are clear patterns of deformity. I collaborated with the Scoliosis Research Society (SRS) and we developed the definitive adult deformity classification system that was based on function and pain."

"We were able to look at patients' progress one, two and three years after surgery and to recognize the essential drivers of what determines good outcomes. So much depends on the way we align the key components of the spine. And if we can reach a point of harmony between the shape of the pelvis, lumbar lordosis, and thoracic kyphosis then we can determine the patients' necessary global alignment. At its core it is a mathematical equation…and our goals need to vary from patient to patient."

And it works well enough that the SRS has adopted it. "Using this software—Surgimap, which is available for free online—we can accurately measure, simulate surgical realignment and implant needs. In addition, algorithms have been developed that let us predict outcomes in over 85% of cases. In a pre-op meeting with the patient we take the image, simulate the surgical correction, and click the patient specific rod order button. At that point Medicrea is prompted to make a custom patient specific rod in titanium or cobalt chromium alloy that is made in the exact shape needed by the patient (typically lead time 7 days). It takes a great deal of guesswork out of the OR. Ideally, surgeons don't have to stand around saying, 'We may need a little

more curvature here…and is the rod bend in the right place?' Up to now, surgeons had to use their hands to bend these very stiff fusion rods and just assume that they were able to form it into the correct shape—but they were never sure if that's what the patient really needs."

Surgimap has taken the guesswork out of the process, says Dr. Schwab, resulting in shorter OR time and sets the stage for better patient outcomes. "To date over 100 surgeries have been done using the Medicrea UNiD rod in conjunction with Surgimap, most of which have been in Europe. After the recent FDA approval, however, more and more are being performed here in the U.S. This is a major step forward. It is a translational technology that links science and patient specific planning to improved operative performance. This raises the bar substantially for surgeons and patients. What has prevented others from developing this? There was insufficient clinical data, the algorithms weren't ready, an adapted planning software was lacking…and this all had to be combined and meet with approval by the FDA. This has finally been accomplished. And it's a great thing for our patients"

Soldiers' Careers Don't Have to End After Joint Surgery "Your career is done," are the words that veterans who have had joint arthroplasty often heard in the past. Thanks to Tad Gerlinger, M.D., an orthopedic surgeon at Midwest Orthopaedics at Rush and winner of a Bronze Star, soldiers with knee injuries can return to their military careers. Dr. Gerlinger tells *OTW*, "In the near past, undergoing a hip or knee replacement would disqualify you from future military service. What a waste this is. We have this vast cadre of experienced, senior people who have had to go in front of a medical evaluation board in order to prove that they are sufficiently fit for service. Given our new technologies and techniques, however, we are increasingly able to return people to their active lifestyles."

"This retrospective study, conducted at the San Antonio Military Medical Center, explored the likelihood of soldiers to return to duty following total joint arthroplasty. We found that 86% of patients were able to return to duty, despite the strenuous lifestyle involved; of those, 70% were deployed to the combat zone and completed a full tour as assigned. Overall, it's been exciting to see people such as military pilots and special operations soldiers reclaiming their careers. Those who have undergone total joint surgery no longer have to stand before a board and explain their situations."

Growing Discs Outside the Body Jeff Wang, M.D. and his team are up to some interesting things in California. Dr. Wang, a professor of orthopedic surgery and neurosurgery at the Keck School of Medicine at the University of Southern California, is pushing the envelope when it comes to growing cells. Dr. Wang tells *OTW*, "There are a number of researchers working on collagen matrices; others are trying to get cells in the disc to transform into growth factors. This goes beyond that work."

Zori Buser, Ph.D. of the University of Southern California, elaborates: "In our recent pilot study we used 3D printed scaffolds to grow bovine nucleus pulposus cells and watched closely to see if the cells 'liked' that environment and would continue growing and building extracellular matrix. Using animal cells for bench studies has advantages such as sufficient numbers and the healthy culture. Furthermore, the bovine cells are to the certain extent similar to human cells so that will be helpful in translating the results. Using healthy cells is the best way to test a scaffold because we want to know if those cells can survive in an artificial environment. We will then go back and harvest the human cells in various stages of degeneration. The issue becomes that when you are dealing with those that are not healthy then you really don't have many cells to work from. As we know intervertebral disc is an acellular organ and it is difficult for cells to overcome the degeneration and rebuild the matrix on their own. Additionally the human disc environment has a very low pH and oxygen, so trying to replicate those conditions is always a challenge.

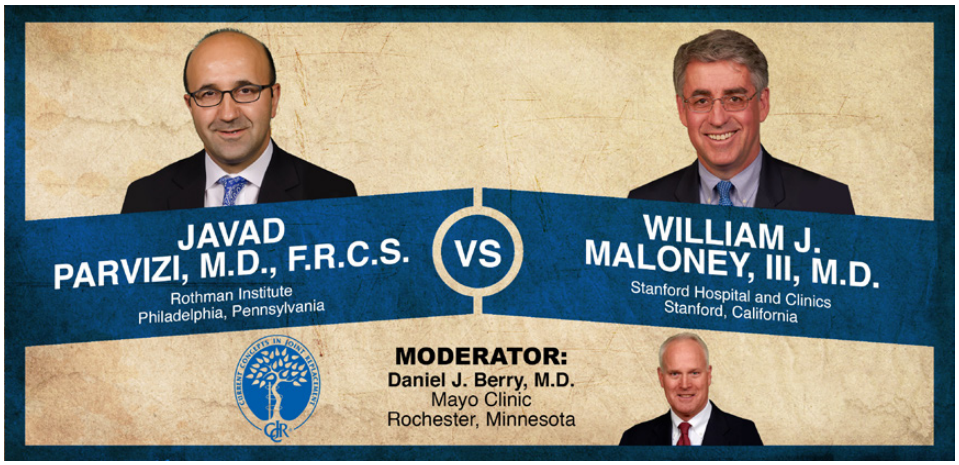
"The 3D printing aspect is very appealing because of the reproducibility. It means we can make hundreds of the same scaffolds without adjusting the chemistry or biology. Our scaffold is a round mesh with different pore sizes and shapes to mimic the disc environment in vivo. In analyzing the initial data we found that this first scaffold is stiff but that the mesh shape plays a role in cell proliferation. The next step will be to combine our 3D scaffolds with one of the matrix proteins (crosslink with collagen) providing a more natural environment to the nucleus pulposus cells."

Dr. Wang adds, "We have just received IRB [institutional review board] approval to do this work using human disc cells from our patients. Our ultimate goal is to be able to grow the disc outside the body and then implant it into the nucleus. We don't yet know how we will attach it to the bone, but we will be addressing that in the near future." ♦

Parvizi v. Maloney Over Direct Anterior

BY ELIZABETH HOFHEINZ, M.P.H., M.ED.

"There isn't a single randomized prospective study showing that the direct anterior is worse than other approaches," says Jay Parvizi. "It's the marketing," says Bill Maloney. "This approach is being pushed by patients because of that. And it's harder clinically…in part because you can't easily visualize the femur."



Current Concepts in Joint Replacement/RRY Photo Creation

This week's Orthopaedic Crossfire® debate was part of a landmark event, the first Brazilian CCJR meeting. The event, which took place in September 2014, was held in Iguassu Falls. This week's Orthopaedic Crossfire® debate is "The Direct Anterior Approach: Optimizes THA Outcome." For the proposition is Javad Parvizi, M.D., F.R.C.S. from the Rothman Institute in Philadelphia, Pennsylvania. Against the proposition is William J. Maloney, III, M.D. from Stanford Hospital and Clinics in California. Moderating is Daniel J. Berry, M.D. of the Mayo Clinic.

Dr. Parvizi: "I think that the direct anterior approach optimizes outcomes. Dr. Maloney is the gladiator of orthopedics, but he will have a difficult time in terms of finding justification for continuing the way we've been going."

"Direct anterior is a tougher technical approach and has to go through its learning curve. But learning curves aren't always bad. In an abdominal aortic aneurism in the early days there were problems and if these innovators had stopped at that point then we wouldn't be doing endovascular surgery to treat abdominal aneurism."

"Dr. Maloney may try to argue that you need a very expensive table in order to perform a direct anterior approach. Not so. My partner and I have never performed the direct anterior approach on a special table. You do need special instruments in order to modify the surgical technique. The direct anterior approach is not the two incision total hip arthroplasty (THA) that has been abandoned by most surgeons based on great articles that came out condemning the two incision technique as not bringing much to orthopedics."

"There are, however, numerous studies on direct anterior. There isn't a single randomized prospective study showing that the direct anterior is worse than other approaches. In order to distill the literature I have used an analytic hierarchy process, something which evaluates the surgical approach based on numerous attributes and then providing a 'spidergram.' If you compare direct lateral with direct anterior, the latter wins in just about every aspect of surgery. In particular, the functional outcome of the direct anterior approach is much better than the direct lateral and the posterolateral approach. There are numerous studies showing that the direct anterior is better than direct lateral and two others that have shown that direct anterior is better than the posterolateral approach."

"Why is it better? It leads to low bleeding, less postoperative pain, shorter length of stay (LOS), faster functional recovery, and shorter operative time (at least at Rothman Institute). So innovation in THA with the use of the direct anterior approach has brought pain control, blood conservation, and faster functional recovery. I would argue that the direct anterior approach is here to stay and it will be one of the most popular approaches in hip arthroplasty in the future. And for those of you who are standing by to see what happens, you might get hurt in the process."

Dr. Maloney: "Jay, Jay…I was easily misled when I was your size. At the risk of introducing some science in to the discussion I'll actually show some data."

"There are definite disadvantages with the anterior approach. It's difficult to visualize the femur, the femoral cuta-

neous nerve often gets injured, there's radiation exposure for both patient and surgeon, leg length equalization is difficult if you use the fracture table, and the learning curve is long."

"Steve Wilson did a study in a community hospital where they introduced the anterior approach; five surgeons compared this approach to the standard length posterior approach. They started the anterior approach mostly for marketing reasons because they were getting pressure from patients to do minimally invasive hip replacement and to reduce their dislocation rates. Four of the five surgeons went and worked with Joel Matta to figure out how to do the operation. They did it Joel's way; they used fluoroscopy and used a fracture table."

"This is what happens in a real world community practice…not at a high volume center where people usually do studies. They accomplished their goal, i.e., they grew their volume. One surgeon's volume increased five times. They increased the percentage of cementless fixation and they started using larger heads—which is primarily the reason for the reduced dislocation and more hard bearings. They used more regional anesthesia and had to use more drains because they were losing more blood, and they allowed the patients to progress quicker. Their surgical time was high. Few studies show that you can do the anterior approach faster than a mini posterior approach."

"For a standard posterior approach it was about two hours and 164 minutes for the anterior approach. Anesthesia time was longer, the LOS decreased by a day, and patients lost more blood. The high volume surgeon probably did the best in terms of decreasing LOS (4 to 2.2 days)."

"The fracture rate was high: 5% in the first 20 cases and about 3% after that. Some of these fractures were significant in terms of delaying patient rehab and affecting the long term outcome. If you examine major complications, it was 9% with anterior versus 2.6% standard posterior approach."

"A friend of mine was at a high volume East Coast institution. This is someone who started out with trochanteric pain, had injections, had an MRI, experienced cartilage loss, and ended up with a bone scan and hip scope. The hip got worse and the X-rays deteriorated; the patient ended up with a total hip replacement through an anterior approach. The first two weeks were no problem, but then the patient had a sudden onset of thigh pain. She

had a back MRI and epidurals…then an X-ray (which looked fine). The pain decreased somewhat, but then pain appeared on the opposite side. But the X-ray wasn't fine; the implant subsided and she had a significant leg length discrepancy. She then had a left hip replaced through an anterior approach and six weeks postop on the left she had persistent groin pain and the socket has changed position."

"They didn't think it was the surgeon, so she got a rheumatology workup and 10 months later she has a revision socket. Later she had her right leg lengthened. She initially has an uneventful recovery, but then she starts to have pain. She gets infected on the right side and gets a head and liner exchange. Fast forward six months and she has pain on the left side and it is infected with a different organism. This is a 50 year old who should be back at work, but because the surgeon used an anterior approach she ends up having 13 operations over two years."

"A study from Mark Pagnano at Mayo on two high volume surgeons who are way past the learning curve; same pain protocol and same rehab protocol comparing direct anterior and mini-posterior approaches. They were pretty much the same, with some slight advantages for the posterior approach in some of the categories. But basically there were insignificant differences."

"The most important thing is getting the parts in right. The current marketing is unethical. Do what you do best."

Moderator Berry: "In the U.S. the numbers are about 60% posterolateral, 20% direct lateral, and about 20% direct anterior. The trend is for posterior to stay pretty steady; anterolateral is going down and direct anterior is increasing. Jay, a problem with the direct anterior is that it constrains surgeons with respect to the implant you can use. Is this inherent in the direct anterior approach?"

Dr. Parvizi: "You need special instruments. As for the acetabular component you can use anything you want. You don't need a special stem."

Moderator Berry: "Bill, the direct anterior in the right hands seems to be doing about a well as the posterior. If you could get people to learn how to do it well could it be here to stay?"

Dr. Maloney: "It's here to stay. The problem is that because of the websites, surgeons feel forced to do it when they're not trained for it or comfortable with it."

Moderator Berry: "Jay, there have been unique complications reported with the direct anterior."

Dr. Parvizi: "Bill is right. You can get lateral femoral cutaneous nerve palsy; that happens in about 20% of my patients. Fortunately it's always transient. Otherwise, I think that many complications happen when you're using the table… when you lose that tactile sense. If you're not careful and you don't have good exposure of the femur because you haven't done the proper exposure then you could crack the femur or malposition the femoral component."

Moderator Berry: "Compared to a posterior approach do you think that there's going to be a substantial, lasting difference in function with the direct anterior approach? Bill?"

Dr. Maloney: "No. Even when you look at the published papers presented at the Hip Society the posterior approach had significant early advantages over the anterior; there was little advantage to the anterior except for slightly higher Harris Hip Scores…but they were a wash after a couple of months."

Moderator Berry: "Jay?"

Dr. Parvizi: "There are four randomized prospective studies showing that the direct anterior approach is better than the posterolateral in the early period."

Moderator Berry: "Are those meaningful differences?"

Dr. Parvizi: "If you have a patient who wants to get back to work within a week or two, I would argue that the person should be given the chance to get back to early function. But by six weeks that might level out. And the Pagnano series…I think that's an unfair comparison. You have a veteran of the posterolateral approach versus someone who just finished fellowship doing direct anterior approach on the table."

Moderator Berry: "Thank you, gentlemen." ♦

Please visit www.CCJR.com to register for the 2015 CCJR Spring Meeting, May 17 - 20 in Las Vegas, Nevada.

COMPANY

Tornier Withdraws and Refiles FTC Notification of Wright Medical Merger

Zimmer Holdings, Inc. and Biomet, Inc. aren't the only two companies caught in the gears of regulatory permission to merge.

Tornier N.V. and Wright Medical Group, Inc. are also trying to weave their way through the Federal Trade Commission (FTC) waiting period required by the Hart-Scott-Rodino (HSR) Antitrust Improvements Act.

On December 30, 2014, Wright Medical announced in an 8-K SEC filing that Tornier had voluntarily withdrawn and refiled its HSR notification and report form relating to the proposed merger. The withdrawal and refiling of the form gives the FTC extra time to review the proposed transaction in the initial phase. The waiting period is now scheduled to expire on Wednesday, January 28, 2015, at 11:59 p.m., unless earlier terminated or a request for additional information or documentary materials is issued to either party prior to the expiration of the waiting period.

The companies announced the planned $3.3 billion merger in October 2014. Each share of Wright will be exchanged for 1.0309 shares of Tornier. Wright shareholders would retain 52% of the combined company.

The new company, Wright Medical N.V. will be headed by current Wright president and CEO Robert Palmisano. Tornier's current president and CEO David Mowry is expected to become executive vice president and COO.

A withdrawal and refiling of FTC notification is not uncommon when FTC staff has raised some issues that the companies believe can be easily resolved with a little extra time.

Good Fourth Quarters

The two companies reported preliminary fourth quarter financial results the week of January 6.

Wright Medical's revenue of $83 million was up 25% over the previous year's fourth quarter on a constant currency basis. The revenue was in line with Wall Street expectations. Tornier, on the other hand, had much better than expected results with revenue of $93 million climbing 15% over the previous year's fourth quarter on a constant currency basis. Tornier's growth was driven by the Aequalis Ascend Shoulder line.

Management of both Tornier and Wright Medical told analysts they remain committed to the deal and continue to expect deal to close in the first half of 2015.

BMO Capital Market analyst Joanne Wuensch said she remains "bullish" on the deal which will create a broad-based extremities company, with $600 million-plus of revenue in 2014, increasing revenue in the low- to mid-teens, with the opportunity for $40-$45 million in cost-cutting opportunities. — *WE*

RRY Publications, Wright Medical Group and Tornier N.V.

LEGAL

Landmark False Claims Decision Shoots Down Whistle-blowers

If a device manufacturer is accused of lying to the FDA about complying with their regulations and then asks Medicare for reimbursement, a whistleblower is likely to sue the manufacturer under the False Claims Act (FCA). If the whistleblower makes a good case, the government is likely to join in.

That's been the basis of many lawsuits, including lawsuits against soon-to-be-Irish-based Medtronic plc and its Infuse product. In that case the whistleblowers say the company cooked the scientific evidence books by paying physicians to say things about the product that weren't true, and then asking for reimbursement. Even a private insurer jumped on that bandwagon and sued the company. The company vehemently denies the accusations.

But according to John Fleder, writing on the *FDA Law Blog* on January 14, 2015, that could all change soon. On January 7, 2015, a judge in California issued a decision, that Fleder says, "May put to rest plaintiffs' efforts to use the FDC (Food, Drug and Cosmetic) Act to support an FCA case."

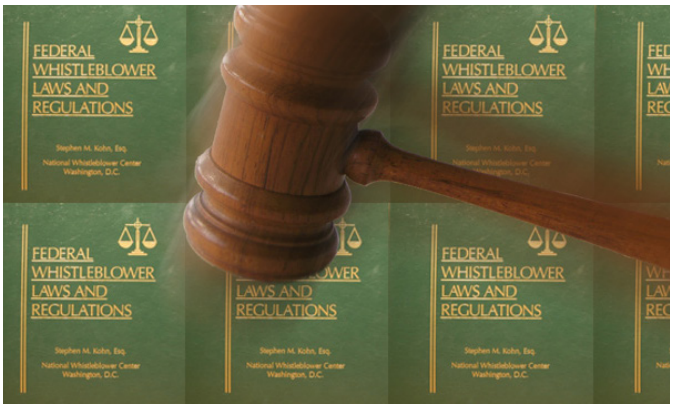


Image created by RRY Publications, LLC

Campie v Gilead Sciences, Inc.

Here is what happened.

Whistleblowers (*U.S. ex rel. Campie v Gilead Sciences, Inc.*, No. 11-0941) in the Northern District of California, alleged that Gilead had violated FDA cGMP regulations and were thus liable under the FCA for submitting claims to Medicare.

"The court methodically went through each of plaintiffs' theories and rejected all of them. These theories included: (1) using an unregistered manufacturing facility; (2) distributing adulterated drugs; (3) making false statements in NDAs [new drug applications], in that impurities in the drugs were not identified in the NDAs; (4) submitting false certificates of analysis that an API was in compliance with cGMPs; and (5) using adulterated drugs in clinical trial products," wrote Fleder.

Where's The False Claim?

Basically the court said that the whistleblowers failed to state a direct link to a false claim. It said there was no evidence that Gilead made any false statement to Centers for Medicare and Medicaid (CMS) for reimbursement. Yes, said the court, the whistleblowers claimed that Gilead lied to the FDA about complying with their regulations, but that does not state a valid False Claims cause of action.

Fleder wrote that the court also said that "even when companies make a purported false certification to a regulatory agency such as FDA, asserting that the company is in compliance with provisions of the FDC Act, that certification cannot in and of itself serve as a basis for an FCA cause of action. Rather **there must be a direct link between the alleged false statement and the resulting request for payment [sic]**, namely that the payment must be conditioned on the falsity. Here, the court concluded that reimbursement by CMS was conditioned only on the drugs having been approved by FDA, not whether Defendants were in compliance with FDA rules."

If the FDA blessed the product and you provide the product to a CMS beneficiary and ask for reimbursement, then there is no false claim. The government can still haul you into court for false statements, but not for false claims.

Second Guessing FDA Approvals

Fleder also wrote the court noted the difficulty of second guessing FDA's decision to approve a drug. "The court refused to delve into what it called 'the complexities, subtleties and variabilities of the FDA approval process,' because the court would have had to determine whether a falsity submitted to FDA would have caused the agency to make a different approval decision than the agency made. 'Violations of for example cGMPs would seem better addressed by the FDA regulatory process than by the blunt tool of FCA litigation.'"

This court ruling, wrote Fleder, "should give comfort to many FDA-regulated companies that although they will continue to face a serious threat of so-called whistleblower suits under the FCA, the cases may well not make their way past a Motion to Dismiss." — *WE*

BIOLOGICS

Israel's Ortho/Pharma Company PolyPid Offers IPO

Israeli-based PolyPid Ltd. has offered a prospectus to raise $18 million-$22 million for an initial public offering (IPO).

The company called off a planned NASDAQ IPO in late 2014 and the $18 million-$22 million is about the same amount the company hoped to raise last year.

The company has developed a delayed-release drug for treatment of compound fractures. According to the company website, PolyPid is an "emerging clinical stage specialty pharmaceutical company engaged in research and development of products based on PLEX (Polymer-Lipid Encapsulation MatriX), our proprietary drug delivery technology. PLEX is able to securely encapsulate many types of drugs, including proteins, to enable targeted, localized drug delivery into the body over periods of time ranging from days to several months."

The problem with existing methods of delivering drugs to bones, according to the company, is the lack of blood flow to the bone, which means that an orally taken drug does not reach the bone in sufficient quantities and last only a short time. They must then be surgically replaced.

PolyPid's technology reportedly facilitates sustained delayed release, and inserting the drug when the fracture is first treated is therefore sufficient. The product has applications in dentistry and in prevention of infections in compound bone fractures.

The PLEX matrix, according to the company, "protects the drug in vivo over extended periods of time without changing the chemistry of the drug. The application of our PLEX technology enables us to optimize drug treatment regimens by providing a unique combination of pre-determined release rates and durations. This combination allows us to create solutions to indications where existing systemic treatments as well as current local treatments are not sufficiently effective or safe, and at the same time to significantly lower the healthcare system economic burden."

Last year, the company reported that a clinical study with PolyPid's leading medical device, BonyPid, an antibiotic-loaded bone substitute, in severe, contaminated open fractures showed "early bone recovery, early soft tissue recovery, no amputations, and high safety profile—no infection in the target fracture."

The product is scheduled to enter clinical trials in 2015 and the company hopes to enter the European market by 2017.

To date, PolyPid has reportedly raised $12.7 million. It lost $3.8 million in 2013 and $2.6 million in the first half of 2014.

The primary shareholders in the company are the Xenia incubator, which has a 16% pre-offering stake; the Friendly Angels club, headed by Adv. Jack Eitan Kyiet, who is also PolyPid's COO (12.4%); inventor and CTO Noam Emanuel (7.1%); CEO and investor Amir Weisberg (5.3%); serial investor Arik Lukach (5.3%); and additional private investors.

In July 2014, the company announced that the U.S. Patent and Trademark Office (USPTO) issued a Notice of Allowance for U.S. application Serial Number 13/574,040, a patent covering compositions for sustained and/or controlled release of nucleic acid agents. A Notice of Allowance is the formal USPTO notification that an applicant is entitled to a patent under the law. — *WE*

PolyPid Ltd.

MTF Adds Wound Care Division

The Musculoskeletal Transplant Foundation (MTF) is launching a new division dedicated to researching and providing allograft-based, biologic solutions to treat acute and chronic wounds. The division is called MTF Wound Care.

MTF is a non-profit that identifies itself as the nation's leading tissue bank that supplies donated human tissue for orthopedics, spine and plastic surgery and sports medicine. Since its founding MTF hs distributed over six million grafts.

Kim Rounds, vice-president of MTF Wound Care, says that the organization will initially offer two forms of tissue, an allograft placental matrix called AmnioBand Membrane and an allograft dermal matrix, called AlloPatch Pliable. Both will be available, she says, in January 2015.

MTF Musculoskeletal Transplant Foundation
Changing Lives Through Tissue Donation

Courtesy of Musculoskeletal Transplant Foundation (MTF)

"These two innovative tissue forms are excellent examples of what we can bring to wound care professionals and their patients," said Rounds. "Both AmnioBand and AlloPatch work in concert with the body's natural healing process. They are the first of what we plan to be a broad and differentiated portfolio of offerings for wound care. Our focus, as always, is to develop solutions that are highly advanced, safe, clinically based and cost effective."

The National Institutes of Health estimates that in the United States more than $25 billion is spent annually to treat chronic wounds. Diabetes is a particular concern because the condition contributes directly and heavily to the wound care problem. The World Health Organization (WHO) estimates that there are 347 million people with diabetes worldwide. That number is expected to rise by 2030.

According to WHO, about 25% of people with diabetes will suffer a lower extremity ulcer over their lifetime. Since healing is typically slow in diabetics, there is an increased risk of infection and a higher risk for amputation. Diabetic ulcers precede 85% of lower extremity amputations. — *BY*

LARGE JOINTS

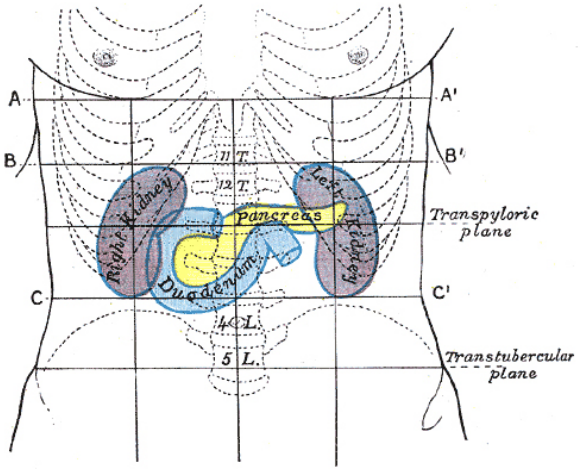
Kidney Injury Associated With Joint Replacement Surgery

An Australian study has found that as many as 15% of elective joint surgery patients at a large hospital have gone on to experience acute kidney injury (AKI) following their surgery. Previous studies of AKI had come up with an incidence rate of approximately 2%.

"In the context that any episode of AKI is associated with increased mortality, longer hospitalization and an increase in the odds of both further episodes of AKI and the later development of chronic kidney disease, an AKI rate of nearly 15% is worrying," wrote lead researcher Lara A. Kimmel, M.D., of the Alfred Hospital in Melbourne, and her colleagues.

According to a report in *Renal & Urology News*, for the study, the researchers examined the medical records of 425 patients who had elective hip or knee replacement surgery at Alfred Hospital between 2011 and June 2013. They established that increasing BMI (body mass index) was the most significant factor. Obesity is an established risk factor for AKI, and the median BMI of this group was over 31 kg/m^2. An older age was also associated with the disease.

The report states that for most patients, AKI resolved by the time the patients were discharged from the hospital. However doctors were aware that an increased mortality risk persists even if renal function recovers. They encourage prospective research to further understand the short- and long-term risks of AKI in the joint replacement population. — *BY*



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FDA Clears hipEOS

Paris-based EOS imaging has announced that the FDA has cleared hipEOS, a 3D hip arthroplasty planning software based on EOS stereo-radiographic 2D/3D imaging. The hipEOS software will have its U.S. launch at the American Academy of Orthopedic Surgeons Annual Meeting from March 24-28 in Las Vegas, Nevada.

As indicated by the company, hipEOS is the first offering of a software portfolio associated with the EOS imaging system; it was developed by OneFit medical, an EOS imaging group company.

A company representative told *OTW*, "The patient's AP [anterior-posterior] and LAT [lateral] images are acquired with EOS during a standard EOS exam, and uploaded on the cloud on a dedicated and protected server. 3D modeling is then performed by EOS imaging 3D service, after which the surgeon can log on the hipEOS page and access to the stereo-radiographic 2D and 3D images, as well as to the 3D pre-op parameters. The software can automatically propose an implant selection and placement from which the surgeon can execute THA [total hip arthroplasty] 3D planning (cup & stem implant size selection, positioning, and specific per-op information required for the surgery such as resection neck measurements). Post-op virtual parameters such as offset and leg length discrepancy are computed automatically in 3D. Once the planning is completed, a planning report is generated to be used during the surgery. hipEOS is the very first, and unique, weight bearing 3D planning software for hip arthroplasty."

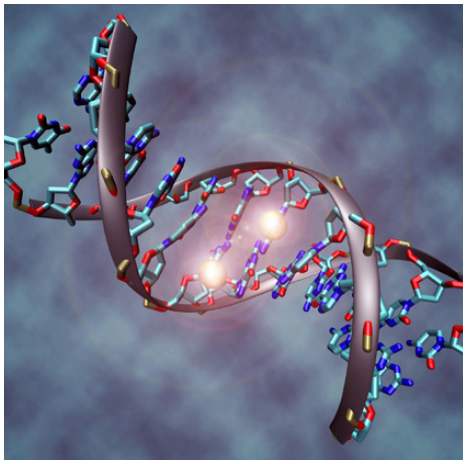
"hipEOS will be offered either directly to our existing and future customers with installed EOS imaging systems, or through orthopedic vendors that will offer the hipEOS planning service in combination with their implants. hipEOS will be first used in selected Centers of Excellence as a pre-launch, and presented during a dedicated symposium at the AAOS meeting and at the EOS booth. Surgeons interested in the service will be able to order through the hipEOS web page and receive log-in credentials."

Marie Meynadier, Ph.D., CEO of EOS imaging, told *OTW*, "The acquisition of OneFit medical in late 2013 reflected our strategy to develop dedicated orthopedics software and tools to EOS customers that capitalized on the EOS imaging system's cutting-edge 3D imaging capabilities, fully utilizing the 3D patient anatomy dataset that is automatically associated with an EOS 3D exam. We are extremely pleased with this first application and the feedback we have received from our early users in Europe is very promising." — *EH*

EOS imaging

Study Affirms Osteoarthritis Not Inheritable

Let the genes off the hook. A family history of osteoarthritis (OA) or unspecified arthralgia was not predictive of developing rheumatoid arthritis (RA) according to a study in Sweden, reported by Diana Swift of *MedPage Today*.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"Although statistically significant familial co-aggregation was found for RA to every non-RA arthritis-related disease group—with no pronounced difference between seropositive and seronegative RA—there was no clinically meaningful association between relatives' arthralgias or osteoarthritis and an individual's risk of RA," wrote Thomas Frisell, Ph.D., of the Karolinska Institute in Solna, and his colleagues. He added that a family history of arthritis-related conditions conferred little or no additional risk.

The researchers made use of Sweden's National Patient Register, and the country's Multi-Generation Register to identify the first-degree relatives of index RA patients. They identified 54,515 people with RA and 203,141 first-degree relatives. Familial conditions studied

included other inflammatory arthritis, juvenile idiopathic arthritis (JIA), spondyloarthropathies, psoriasis/psoriatic arthritis, lupus, connective tissue diseases, arthralgias, and OA.

The researchers found that the co-aggregation pattern of arthritis-related diseases was very similar for seropositive and seronegative RA. "The difference between seropositive and seronegative RA was significant for only two of the non-RA diseases—spondyloarthropathies and psoriasis/psoriatic arthritis," the authors wrote.

The investigators did find that some familial conditions were more strongly associated with RA. For example, a family history of juvenile idiopathic arthritis or a first-degree relative with lupus or connective tissue disease might be predictive. There were no marked differences among siblings, parents and offspring where familial risk was concerned. A consortium of Swedish research institutions sponsored the study. — *BY*

About Time! International Registry to Monitor Implants

The identifying initials are ICOR and they stand for International Consortium of Orthopedic Registries—a new and somewhat unprecedented collaboration among researchers. Purpose of the registry is to track the effectiveness and safety of hip and knee implants after they have been installed. The researchers and data collectors are from the U.S. institutions Kaiser Permanente and Weill Cornell Medical College and registries in Australia, Spain, Italy, Sweden, and Norway.

Wikimedia commons and Daniel Mietchen

From the perspective of consumers, it is about time.

"In orthopedics, large registries or networks of registries capture device information on a very detailed level and can become particularly important for active surveillance and post-market evaluation," said Art Sedrakyan, M.D., Ph.D., associate professor of health care policy and research at Weill Cornell Medical College. "Comparative studies of hip and knee devices illustrate the ability of a registry consortium to determine real-world evidence for various classes of devices and help surgeons and patients to make evidence-based choices."

According to a report by *PR Newswire*, prior research had found that almost no electronic health record system can automatically identify devices and link them to an individual patient's outcome data—but registries can. Because of this, the FDA has made the development of device registries and the creation of a device identification (UDI) system for medical devices a key priority.

"ICOR's achievements to date have enormous implications for medical device post-market surveillance system development in the United States and worldwide," said Liz Paxton, director of Kaiser Permanente's Surgical Outcomes and Analysis Unit of Clinical Analysis. "Its ability to create an international, distributed research network in the field of medical devices opens a new door for evidence development and device-safety investigations," she told PR Newswire. — *BY*

Study Advocates Better Post-Op Pain Control

According to one estimate, more than half of the adults in the U.S. who are diagnosed with knee osteoarthritis will go on to have knee replacement surgery. Pain control after the surgery remains a persistent side effect for patients.

A Henry Ford Hospital study found that injecting a long-acting numbing medicine—called liposomal bupivacaine—into the tissue surrounding the knee during surgery may provide faster recovery and higher patient satisfaction.

In the Henry Ford study, doctors evaluated 216 patients for pain control the first two days after surgery from October 2012 to September 2013. Half of the patients received the traditional pain control method with continuous femoral nerve blockade, in which common numbing medicine is injected into the groin area, blunting the main nerve down the front of the knee. This method uses a pain pump to extend pain control for two days but causes some leg weakness. "Pain control came at the price of weakness and made patients somewhat tentative when walking during their hospital stay," according to Jason Davis, M.D., a Henry Ford West Bloomfield Hospital joint replacement surgeon and the study's senior author, in the December 2015 press release.

The other half of patients received the liposomal bupivacaine injection at the site of the surgery. Many of these patients were able to walk comfortably within hours after surgery.

Davis said that the injection around the knee itself "optimizes pain control early on" without the side effects of the traditional technique. "Function-wise, it was a lot easier for patients to move around more confidently. In the past decade, we've made major advancements in pain control for knee replacement surgery. This option is a promising, viable one for our patients."

He added, "The pain scores for this injection technique averaged about 3/10, which is similar to the pain scores seen with our traditional method. "Patients had pain relief for up to two days after surgery and better knee function compared with the traditional method." — *BY*

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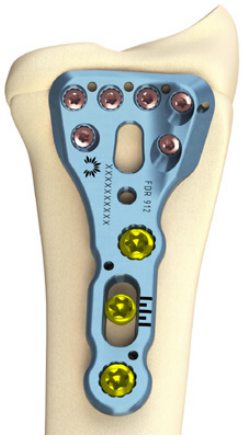
EXTREMITIES

New Distal Radius Implant From Flower Orthopedics

Flower Orthopedics Corporation released a new "FlowerCube" anatomic distal radius plate with instruments on January 13, 2015.



Distal Radius Plate/Flower Orthopedics Corporation

The company developed the "Ready-for-Surgery" FlowerCube concept which provides implants in individual sterile packaging. According to the company, this eliminates the need for pre-op sterilization and "considerably" reduces the number of implants and instruments brought into the operating room. All the instruments are single-use and disposable. The company claims that hospitals and ambulatory surgical centers can save as much as 30% of the combined implant and instrument costs currently spent on cases.

"The anatomic distal radius plates and the new disposable instruments from Flower represent the latest evolution of the FlowerCube concept and provide an economic, efficient and versatile solution for treatment of distal radius fractures. The versatility of the plating system combined with the benefits of

the Flower Ready-for-Surgery concept increase the efficiency of operative distal radius fracture management", said Tim Niacaris, M.D., Chief of Hand Surgery at the JPS Health Network in Fort Worth, Texas, in a company press release.

According to the company, the plate belongs to the Flower Small/Medium Implant set that has been FDA cleared for "internal fixation of fractures and reconstruction of bones, including the scapula, olecranon, humerus, radius, ulna, pelvis, distal tibia, fibula, hand and foot in adults and in adolescents (12-21) in whom the growth plates have fused. Examples of these internal fixations and reconstructions include compression fractures, intra-articular and extra articular fractures, displaced fractures, osteotomies, non-unions and mal-unions. The system can be used for palmar, ventral, dorsal or orthogonal application."

Features of the implant described by the company include:

- Low profile and rounded plate edges
- Countersunk screws to reduce the risk of soft tissue irritation
- Anatomically contoured to sit flush on bone
- Targeted screw placement for fragment specific fixation
- Oblong hole with measurement marks
- Variable-angle locking and non-locking
- Targeted K-Wire holes
- Plate options: left, right
- Plate types: narrow, standard

Flower Orthopedics was co-founded in 2012 by Oliver Burckhardt and Josef Zrinski. The company's implants and instruments are manufactured by German-based Zrinski AG. — *WE*

TRAUMA

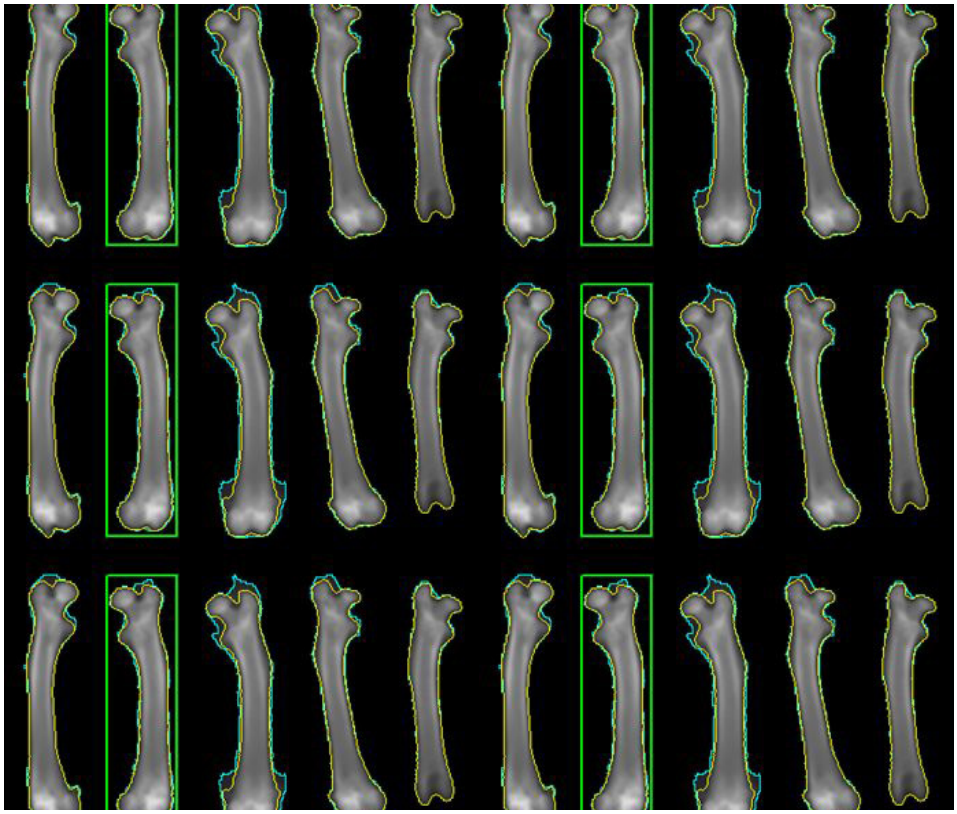
Life Satisfaction = Higher Bone Density

New research from Finland indicates that being happy in life may translate to stronger bones. The work, which included 2,167 women, found that women aged 60-70 who are satisfied with their lives have a higher bone density and they suffer from osteoporosis less frequently than their unsatisfied peers. The research was completed at the University of Eastern Finland.

According to the January 13, 2015 news release, the data was obtained from the Kuopio Osteoporosis Risk Factor and Prevention (OSTPRE) Study. Out of the 2,167 women who underwent bone density measurements in 1999, 1,147 took part in follow-up measurements ten years later, in 2009. Participants were asked questions relating to the interest in and easiness of life, happiness, and loneliness. This resulted in three groups: the satisfied, the middle group, and the unsatisfied.

"During the 10-year follow-up, the bone density of all study participants weakened by an average of 4%; however, the difference between the satisfied and the unsatisfied was as much as 52%. Changes in life satisfaction during the 10-year follow-up also affected bone density. In persons whose life satisfaction deteriorated, the bone density weakened by 85% in comparison to persons whose life satisfaction improved."

The study constitutes part of the Ph.D. project of researcher Päivi Rauma, M.Pharm., focusing on the effects of depression, anti-depressants and life satisfaction on bone health. — *EH*



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SPINE

Spinal Simplicity Claims First FDA Clearance Using Percutaneous Lateral Approach

Overland Park, Kansas-based Spinal Simplicity, LLC, claims it has the only ISP (interspinous process) fusion device utilizing a percutaneous lateral approach to the spine cleared by the FDA for U.S. patients.

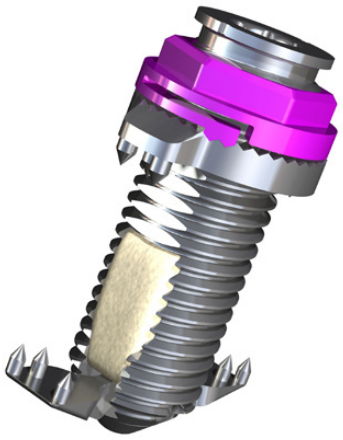
On January 9, 2015, the company announced the 510(k) FDA clearance of its Minuteman lateral percutaneous interlaminar fusion device.

The Minuteman

The device, according to the company, is a "pre-packaged sterile supplemental posterior fixation system" which offers a "minimally invasive alternative to traditional pedicle screws and other spinous process plates" placed in open procedures for the treatment of degenerative disc disease, spondylolisthesis, tumors and/or trauma. The system can be placed in patients utilizing two minimally invasive approaches to the spine, posterior unilateral or "lateral percutaneous (PercLIF-Percutaneous Lateral Interlaminar Fusion)."

While the company used several ISP fusion devices as predicate devices to gain FDA 510(k) clearance, Carlos Gonzalez, the company's director of sales and marketing, told *OTW* that Lanx's (Biomet, Inc.) Aspen device was used as the main predicate.

The PercLIF approach and instrumentation provide a way of "quickly and accurately placing the Minuteman between the spinous processes through



Minuteman lateral percutaneous interlaminar fusion device, courtesy of Spinal Simplicity, LLC

a one-inch incision. This technique eliminates the lateral dissection of sensitive back muscles often associated with lumbar fusions while maintaining an adequate distance from the neural structures," said the company.

Todd Moseley, a co-founder of the company said the lateral approach is "one of the many" potential benefits of the Minuteman system. "Direct lateral surgeons will now have the ability to insert a supplemental posterior fixation device with the patient remaining in the lateral decubitous position, typically in about 10 to 15 minutes. As a team, Spinal Simplicity believes this flagship product will provide the foundation for further innovation in the minimally invasive spine market."

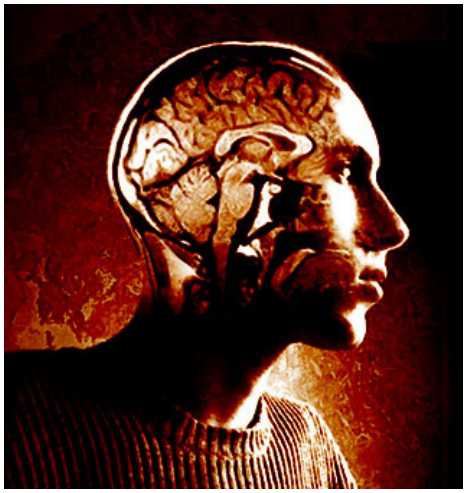
The company anticipates commercial launch of the Minuteman system in the first quarter of 2015. The company began selling the product in Europe in 2011 after receiving a CE Mark.

Spinal Simplicity was founded in 2008 by Moseley and Harold Hess, M.D., a neurosurgeon. The company says it dedicated to creating "innovative" and "simple" solutions for complex problems. — *WE*

Study Challenges Minimally Invasive Spine Surgery

A Canadian study has found that there are no long-term beneficial outcomes between minimally invasive and open discectomies. In fact, minimally invasive surgery for discectomies may be associated with greater risks of neurologic injury and incidental damage to the covering of the spinal cord, according to a McMaster University press release.

Nathan Evaniew, a research fellow in orthopedics and a Ph.D. student in health research methodologies at McMaster University's Michael G. DeGroote School of Medicine in Hamilton, Ontario, led the study.



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"Surgeons already perform open discectomies through relatively small incisions. Selecting the right patients and providing technically adequate nerve-root decompression are probably the most important determinants of long-term outcomes," said Evaniew in the press release. "We were not surprised to find that outcomes are essentially the same between minimally invasive and open discectomies."

The study concluded that "current evidence does not support the routine use of minimally invasive surgery to remove herniated disc material pressing on the nerve root or spinal cord in the neck or lower back."

On the positive side, the researchers found that minimally invasive surgery for cervical or lumbar discectomy may speed up recovery and reduce post-operative pain. "Surgeons already perform open discectomies through relatively small incisions. Selecting the right patients and providing technically adequate nerve-root decompression are probably the most important determinants of long-term outcomes," said Evaniew.

In their study Evaniew and his fellow researchers searched the MEDLINE, Embase and Cochrane Library databases of relevant randomized controlled trials and reviewed four trials involving 431 patients in the cervical discectomy group, and 10 trials involving 1,159 patients in the lumbar discectomy group. They noted that both forms of spinal surgery are technically difficult to master, with difficult learning curves. They urged further well-designed trials on both procedures. — *BY*

PEOPLE

Keith Valentine Leaving NuVasive; Pat Miles Taking Over

NuVasive, Inc. has announced that its Chief Operating Officer (COO) Keith Valentine, will step down leave the company as of April 30, 2015. Pat Miles, NuVasive's current president of Global Products and Services, will assume an expanded role as President and COO.

Valentine told *OTW*, "Helping to grow NuVasive from no revenues to a company that is quickly approaching $1 billion in revenues has been an extraordinary experience and a privilege to serve so many dedicated shareowners committed to changing spine surgery, and departing the company is a personal decision for me. The challenging and dynamic nature of start-up businesses has a tremendous appeal to me and—with the great learning opportunity and dynamic teams I've been able to experience at Nuvasive—I'm now looking to fulfill long-held professional aspirations that will focus on that start-up mentality with the goal of leading a company through the evolution of its growth."

"The most important lesson I've learned at NuVasive is the value of a strong and contagious corporate culture. The company's shareowners are completely invested in the company's success and it is key competitive advantage at NuVasive [that] continues to drive the most innovative and disruptive procedural solutions in spine."

Pat Miles will continue to be responsible for leadership and management of global products and services. In addition, he will take on NuVasive's operational duties, including customer fulfillment, manufacturing, supply chain management and quality engineering.

Miles told *OTW*, "Our ability to adapt and transform to the rapidly shifting and dynamic markets in which we participate is essential to our success. My first priority will be to ensure that our operating structure matches our growth strategy as we continue to rapidly scale the business. The successful integration of global products and services function with operational activities will fuel our market share-taking strategy to be executed over the next five years, positioning NuVasive competitively as an innovator and disruptor in spine."

The January 12, 2015 news release indicated that Matt Link, currently executive vice president of U.S. Sales, will become president of U.S. Sales and Services and will lead an expanded team. The company will be integrating and aligning all "U.S. field personnel to form a combined sales and services organization. This will include the consolidation of the company's field sales, clinical associates, IMI [Impulse Monitoring Inc.] neurophysiologists and monitoring contracting."— *EH*

Keith Valentine/ NuVasive, Inc.

Pat Miles/ NuVasive, Inc.

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